FEDERAL REGULATONS CROSS-REFERENCED IN CONTRACT

Various Parts related to PART 438—MANAGED CARE

Sec. 422.128 Information on Advance Directives

(a) Each M+C organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in subpart I of part 489 of this chapter. For purposes of this part, advance directive has the meaning given the term in Sec. 489.100 of this chapter.
(b) An M+C organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the M+C organization.
(1) An M+C organization must provide written information to those individuals with respect to the following:
(i) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Providers may contract with other entities to furnish this information but remain legally responsible for ensuring that the requirements of this section are met. The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.
(ii) The M+C organization's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the M+C organization cannot implement an advance directive as a matter of conscience. At a minimum, this statement must do the following:
(A) Clarify any differences between institution-wide conscientious objections and those that may be raised by individual physicians.
(B) Identify the state legal authority permitting such objection.
(C) Describe the range of medical conditions or procedures affected by the conscience objection.
(D) Provide the information specified in paragraph (a)(1) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the M+C organization may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The M+C organization is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.
(E) Document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive.
(F) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.
(G) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives.
(H) Provide for education of staff concerning its policies and procedures on advance directives.

(l) Provide for community education regarding advance directives that may include material required in paragraph (a)(1)(i) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the M+C organization. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An M+C organization must be able to document its community education efforts.
(2) The M+C organization--
(i) Is not required to provide care that conflicts with an advance directive; and
(ii) Is not required to implement an advance directive if, as a matter of conscience, the M+C organization cannot implement an advance directive and State law allows any health care provider or any agent of the provider to conscientiously object.
(3) The M+C organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

Sec. 489.100 Definition.

For purposes of this part, advance directive means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.

Sec. 431.244 Hearing decisions.
. . . .
(f) The agency must take final administrative action as follows:
(1) Ordinarily, within 90 days from the earlier of the following:
(i) The date the enrollee filed an MCO or PIHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing; or
(ii) If permitted by the State, the date the enrollee filed for direct access to a State fair hearing.
(2) As expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, from the MCO or PIHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PIHP—
(i) Meets the criteria for expedited resolution as set forth in Sec. 438.410(a) of this chapter, but was not resolved within the timeframe for expedited resolution; or
(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.
(3) If the State agency permits direct access to a State fair hearing, as expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, directly from an MCO or PIHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in Sec. 438.410(a) of this chapter. . . .

PART 438—MANAGED CARE
Subpart A—General Provisions

Sec. 438.6 Contract requirements.

(a) Regional office review. The CMS Regional Office must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in Sec. 438.806.
(b) Entities eligible for comprehensive risk contracts. (N/A)
(c) Payments under risk contracts. (N/A)

(d) Enrollment discrimination prohibited. (N/A)
(f) Compliance with contracting rules. All contracts under this subpart must:
(1) Comply with all applicable Federal and State laws and regulations including title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act; and
(2) Meet all the requirements of this section.
(g) Inspection and audit of financial records. Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.
(h) Physician incentive plans.
(1) MCO, PIHP, and PAHP contracts must provide for compliance with the requirements set forth in Secs. 422.208 and 422.210 of this chapter.
(2) In applying the provisions of Secs. 422.208 and 422.210 of this chapter, references to ``M+C organization'', ``CMS'', and ``Medicare beneficiaries'' must be read as references to ``MCO, PIHP, or PAHP'', ``State agency'' and ``Medicaid recipients'', respectively.
(i) Advance directives.
(1) All MCO and PIHP contracts must provide for compliance with the requirements of Sec. 422.128 of this chapter for maintaining written policies and procedures for advance directives.
(2) All PAHP contracts must provide for compliance with the requirements of Sec. 422.128 of this chapter for maintaining written policies and procedures for advance directives if the PAHP includes, in its network, any of those providers listed in Sec. 489.102(a) of this chapter.
(3) The MCO, PIHP, or PAHP subject to this requirement must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.
(4) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.
(j) Special rules for certain HIOs. (N/A)
(k) Additional rules for contracts with PCCMs. (N/A)
(l) Subcontracts. All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.
(m) Choice of health professional. The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

Sec. 438.10 Information requirements.
(a) Terminology. As used in this section, the following terms have the indicated meanings:
Enrollee means a Medicaid recipient who is currently enrolled in an MCO, PIHP, PAHP, or PCCM in a given managed care program.
Potential enrollee means a Medicaid recipient who is subject to mandatory enrollment or may voluntarily elect to enroll in a given managed care program, but is not yet an enrollee of a specific MCO, PIHP**,** PAHP, or PCCM.
(b) Basic rules.

(1) Each State, enrollment broker, MCO, PIHP, PAHP, and PCCM must provide all enrollment notices, informational materials, and instructional materials relating to enrollees and potential enrollees in a manner and format that may be easily understood.
(2) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.
(3) Each MCO and PIHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.
(c) Language. The State must do the following:
(1) Establish a methodology for identifying the prevalent non- English languages spoken by enrollees and potential enrollees throughout the State. ``Prevalent'' means a non-English language spoken by a significant number or percentage of potential enrollees and enrollees in the State.
(2) Make available written information in each prevalent non- English language.
(3) Require each MCO, PIHP, PAHP, and PCCM to make its written information available in the prevalent non-English languages in its particular service area.
(4) Make oral interpretation services available and require each MCO, PIHP, PAHP, and PCCM to make those services available free of charge to each potential enrollee and enrollee. This applies to all non-English languages, not just those that the State identifies as prevalent.
(5) Notify enrollees and potential enrollees, and require each MCO, PIHP, PAHP, and PCCM to notify its enrollees—
(i) That oral interpretation is available for any language and written information is available in prevalent languages; and
(ii) How to access those services.
(d) Format. (1) Written material must—
(i) Use easily understood language and format; and
(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.
(2) All enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats.
(e) Information for potential enrollees.
(1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee as follows:
(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary program, or is first required to enroll in a mandatory enrollment program.
(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHP, PAHPs, or PCCMs.
(2) The information for potential enrollees must include the following:
(i) General information about—
(A) The basic features of managed care;
(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program; and
(C) MCO, PIHP, PAHP, and PCCM responsibilities for coordination of enrollee care;
(ii) Information specific to each MCO, PIHP, PAHP, or PCCM program operating in potential enrollee's service area. A summary of the following information is sufficient, but the State must provide more detailed information upon request:
(A) Benefits covered.
(B) Cost sharing, if any.
(C) Service area.

(D) Names, locations, telephone numbers of, and non-English language spoken by current contracted providers, and including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs, this includes at a minimum information on primary care physicians, specialists, and hospitals.
(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service.
(f) General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs. Information must be furnished to MCO, PIHP, PAHP, and PCCM enrollees as follows:
(1) The State must notify all enrollees of their disenrollment rights, at a minimum, annually. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 days before the start of each enrollment period.
(2) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must notify all enrollees of their right to request and obtain the information listed in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least once a year.
(3) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must furnish to each of its enrollees the information specified in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, within a reasonable time after the MCO, PIHP**,** PAHP, or PCCM receives, from the State or its contracted representative, notice of the recipient's enrollment.
(4) The State, its contracted representative, or the MCO, PIHP**,** PAHP, or PCCM must give each enrollee written notice of any change (that the State defines as ``significant'') in the information specified in paragraphs (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least 30 days before the intended effective date of the change.
(5) The MCO, PIHP, and, when appropriate, the PAHP or PCCM, must make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.
(6) The State, its contracted representative, or the MCO, PIHP**,** PAHP, or PCCM must provide the following information to all enrollees:
(i) Names, locations, telephone numbers of, and non-English languages spoken by current contracted providers in the enrollee's service area, including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists, and hospitals.
(ii) Any restrictions on the enrollee's freedom of choice among network providers.
(iii) Enrollee rights and protections, as specified in Sec. 438.100.
(iv) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in Sec. 438.10(g)(1), and for PAHP enrollees, the information specified in Sec. 438.10(h).
(v) The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.
(vi) Procedures for obtaining benefits, including authorization requirements.
(vii) The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.
(viii) The extent to which, and how, after-hours and emergency coverage are provided, including:
(A) What constitutes emergency medical condition, emergency services, and poststabilization services, with reference to the definitions in Sec. 438.114(a).

(B) The fact that prior authorization is not required for emergency services.
(C) The process and procedures for obtaining emergency services, including use of the 911-telephone system or its local equivalent.
(D) The locations of any emergency settings and other locations at which providers and hospitals furnish emergency services and poststabilization services covered under the contract.
(E) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.
(ix) The poststabilization care services rules set forth at Sec. 422.113(c) of this chapter.
(x) Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.
(xi) Cost sharing, if any.
(xii) How and where to access any benefits that are available under the State plan but are not covered under the contract, including any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM need not furnish information on how and where to obtain the service. The State must provide information on how and where to obtain the service.
(g) Specific information requirements for enrollees of MCOs and PIHPs. In addition to the requirements in Sec. 438.10(f), the State, its contracted representative, or the MCO and PIHP must provide the following information to their enrollees:
(1) Grievance, appeal, and fair hearing procedures and timeframes, as provided in Secs. 438.400 through 438.424, in a State-developed or State-approved description, that must include the following:
(i) For State fair hearing—
(A) The right to hearing;
(B) The method for obtaining a hearing; and
(C) The rules that govern representation at the hearing.
(ii) The right to file grievances and appeals.
(iii) The requirements and timeframes for filing a grievance or appeal.
(iv) The availability of assistance in the filing process.
(v) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.
(vi) The fact that, when requested by the enrollee—
(A) Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and
(B) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.
(vii) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.
(2) Advance directives, as set forth in Sec. 438.6(i)(2).
(3) Additional information that is available upon request, including the following:
(i) Information on the structure and operation of the MCO or PIHP.
(ii) Physician incentive plans as set forth in Sec. 438.6(h) of this chapter.
(h) Specific information for PAHPs. . . ..
(i) Special rules: States with mandatory enrollment under State plan authority—. . . .

Subpart C--Enrollee Rights and Protections

Sec. 438.100 Enrollee rights.
(a) General rule. The State must ensure that—

(1) Each MCO and PIHP has written policies regarding the enrollee rights specified in this section; and
(2) Each MCO, PIHP, PAHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account when furnishing services to enrollees.
(b) Specific rights—
(1) Basic requirement. The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.
(2) An enrollee of an MCO, PIHP**,** PAHP, or PCCM has the following rights: The right to –
(i) Receive information in accordance with Sec. 438.10.
(ii) Be treated with respect and with due consideration for his or her dignity and privacy.
(iii) Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in Sec. 438.10(f)(6)(xiii).)
(iv) Participate in decisions regarding his or her health care, including the right to refuse treatment.
(v) Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.
(vi) If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR Sec. 164.524 and 164.526.
(3) An enrollee of an MCO, PIHP**,** or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with Secs. 438.206 through 438.210.
(c) Free exercise of rights. The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PIHP**,** PAHP, or PCCM and its providers or the State agency treat the enrollee.
(d) Compliance with other Federal and State laws. The State must ensure that each MCO, PIHP**,** PAHP, and PCCM complies with any other applicable Federal and State laws (such as: title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and titles II and III of the Americans with Disabilities Act; and other laws regarding privacy and confidentiality).

Subpart D--Quality Assessment and Performance Improvement

Sec. 438.204 Elements of State quality strategies.
At a minimum, State strategies must include the following:
(a) The MCO and PIHP contract provisions that incorporate the standards specified in this subpart.
(b) Procedures that—
(1) Assess the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PIHP contracts, and to individuals with special health care needs.
(2) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PIHP for each Medicaid enrollee at the time of enrollment.
(3) Regularly monitor and evaluate the MCO and PIHP compliance with the standards.

(c) For MCOs and PIHPs, any national performance measures and levels that may be identified and developed by CMS in consultation with States and other relevant stakeholders.
(d) Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each MCO and PIHP contract.
(e) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.
(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.
(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

Sec. 438.240 Quality assessment and performance improvement program.
(a) General rules.
(1) The State must require, through its contracts, that each MCO and PIHP have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.
(2) CMS, in consultation with States and other stakeholders, may specify performance measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PIHPs.
(b) Basic elements of MCO and PIHP quality assessment and performance improvement programs. At a minimum, the State must require that each MCO and PIHP comply with the following requirements:
(1) Conduct performance improvement projects as described in paragraph (d) of this section. These projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction.
(2) Submit performance measurement data as described in paragraph (c) of this section.
(3) Have in effect mechanisms to detect both underutilization and overutilization of services.
(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.
(c) Performance measurement. Annually each MCO and PIHP must—
(1) Measure and report to the State its performance, using standard measures required by the State including those that incorporate the requirements of Sec. 438.204(c) and Sec. 438.240(a)(2);
(2) Submit to the State, data specified by the State, that enables the State to measure the MCO's or PIHP's performance; or
(3) Perform a combination of the activities described in paragraphs (c)(1) and (c)(2) of this section.
(d) Performance improvement projects.
(1) MCOs and PIHPs must have an ongoing program of performance improvement projects that focus on clinical and nonclinical areas, and that involve the following:
(i) Measurement of performance using objective quality indicators.
(ii) Implementation of system interventions to achieve improvement in quality.
(iii) Evaluation of the effectiveness of the interventions.
(iv) Planning and initiation of activities for increasing or sustaining improvement.
(2) Each MCO and PIHP must report the status and results of each project to the State as requested, including those that incorporate the requirements of Sec. 438.240(a)(2). Each performance improvement project must be completed in a reasonable time period so as to

generally allow information on the success of performance improvement projects in the aggregate to produce new information on quality of care every year.
(e) Program review by the State.
(1) The State must review, at least annually, the impact and effectiveness of each MCO's and PIHP's quality assessment and performance improvement program. The review must include—
(i) The MCO's and PIHP's performance on the standard measures on which it is required to report; and
(ii) The results of each MCO's and PIHP's performance improvement projects.
(2) The State may require that an MCO or PIHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

Subpart F--Grievance System
(Please note that not all provisions apply to Mental Health Plans per approved waiver renewal request. See contract terms to identify specific requirements of the MHPs.)

Sec. 438.400 Statutory basis and definitions.
(a) Statutory basis. This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4) of the Act.
(1) Section 1902(a)(3) requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.
(2) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.
(3) Section 1932(b)(4) requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.
(b) Definitions. As used in this subpart, the following terms have the indicated meanings:
Action means-- In the case of an MCO or PIHP—
(1) The denial or limited authorization of a requested service, including the type or level of service;
(2) The reduction, suspension, or termination of a previously authorized service;
(3) The denial, in whole or in part, of payment for a service;
(4) The failure to provide services in a timely manner, as defined by the State;
(5) The failure of an MCO or PIHP to act within the timeframes provided in Sec. 438.408(b); or
(6) For a resident of a rural area with only one MCO, the denial of a Medicaid enrollee's request to exercise his or her right, under Sec. 438.52(b)(2)(ii), to obtain services outside the network.
Appeal means a request for review of an action, as "action" is defined in this section.
Grievance means an expression of dissatisfaction about any matter other than an action, as "action" is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PIHP level and access to the State fair hearing process. (Possible subjects for grievances include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.)

Sec. 438.402 General requirements.
(a) The grievance system. Each MCO and PIHP must have a system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system.
(b) Filing requirements—
(1) Authority to file.—

(i) An enrollee may file a grievance and an MCO or PIHP level appeal, and may request a State fair hearing.
(ii) A provider, acting on behalf of the enrollee and with the enrollee's written consent, may file an appeal. A provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.
(2) Timing. The State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PIHP's notice of action. Within that timeframe—
(i) The enrollee or the provider may file an appeal; and
(ii) In a State that does not require exhaustion of MCO and PIHP level appeals, the enrollee may request a State fair hearing.
(3) Procedures.
(i) The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PIHP.
(ii) The enrollee or the provider may file an appeal either orally or in writing, and unless he or she requests expedited resolution, must follow an oral filing with a written, signed, appeal.

Sec. 438.404 Notice of action.
(a) Language and format requirements. The notice must be in writing and must meet the language and format requirements of Sec. 438.10(c) and (d) to ensure ease of understanding.
(b) Content of notice. The notice must explain the following:
(1) The action the MCO or PIHP or its contractor has taken or intends to take.
(2) The reasons for the action.
(3) The enrollee's or the provider's right to file an MCO or PIHP appeal.
(4) If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.
(5) The procedures for exercising the rights specified in this paragraph.
(6) The circumstances under which expedited resolution is available and how to request it.
(7) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances under which the enrollee may be required to pay the costs of these services.
(c) Timing of notice. The MCO or PIHP must mail the notice within the following timeframes:
(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in Secs. 431.211, 431.213, and 431.214 of this chapter.
(2) For denial of payment, at the time of any action affecting the claim.
(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in Sec. 438.210(d)(1).
(4) If the MCO or PIHP extends the timeframe in accordance with Sec. 438.210(d)(1), it must—
(i) Give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and
(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.
(5) For service authorization decisions not reached within the timeframes specified in Sec. 438.210(d) (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.
(6) For expedited service authorization decisions, within the timeframes specified in Sec. 438.210(d).

Sec. 438.406 Handling of grievances and appeals.

(a) General requirements. In handling grievances and appeals, each MCO and each PIHP must meet the following requirements:

(1) Give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes, but is not limited to, providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(2) Acknowledge receipt of each grievance and appeal.

(3) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were not involved in any previous level of review or decision-making; and

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(b) Special requirements for appeals. The process for appeals must:

(1) Provide that oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(2) Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing. (The MCO or PIHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)

(3) Provide the enrollee and his or her representative opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

(4) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

Sec. 438.408 Resolution and notification: Grievances and appeals.

(a) Basic rule. The MCO or PIHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) Specific timeframes.—

(1) Standard disposition of grievances. For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 days from the day the MCO or PIHP receives the grievance.

(2) Standard resolution of appeals. For standard resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer than 45 days from the day the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(3) Expedited resolution of appeals. For expedited resolution of an appeal and notice to affected parties, the State must establish a timeframe that is no longer than 3 working days after the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) Extension of timeframes.—

(1) The MCO or PIHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) Requirements following extension. If the MCO or PIHP extends the timeframes, it must--for any extension not requested by the enrollee, give the enrollee written notice of the reason for the delay.
(d) Format of notice.—
(1) Grievances. The State must establish the method MCOs and PIHPs will use to notify an enrollee of the disposition of a grievance.
(2) Appeals.
(i) For all appeals, the MCO or PIHP must provide written notice of disposition.
(ii) For notice of an expedited resolution, the MCO or PIHP must also make reasonable efforts to provide oral notice.
(e) Content of notice of appeal resolution. The written notice of the resolution must include the following:
(1) The results of the resolution process and the date it was completed.
(2) For appeals not resolved wholly in favor of the enrollees—
(i) The right to request a State fair hearing, and how to do so;
(ii) The right to request to receive benefits while the hearing is pending, and how to make the request; and
(iii) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PIHP's action.
(f) Requirements for State fair hearings.—
(1) Availability. The State must permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days from whichever of the following dates applies—
(i) If the State requires exhaustion of the MCO or PIHP level appeal procedures, from the date of the MCO's or PIHP's notice of resolution; or
(ii) If the State does not require exhaustion of the MCO or PIHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PIHP's notice of action.
(2) Parties. The parties to the State fair hearing include the MCO or PIHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

Sec. 438.410 Expedited resolution of appeals.
(a) General rule. Each MCO and PIHP must establish and maintain an expedited review process for appeals, when the MCO or PIHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.
(b) Punitive action. The MCO or PIHP must ensure that punitive action is neither taken against a provider who requests an expedited resolution or supports an enrollee's appeal.
(c) Action following denial of a request for expedited resolution. If the MCO or PIHP denies a request for expedited resolution of an appeal, it must—
(1) Transfer the appeal to the timeframe for standard resolution in accordance with Sec. 438.408(b)(2);
(2) Make reasonable efforts to give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice.

Sec. 438.414 Information about the grievance system to providers and subcontractors.
The MCO or PIHP must provide the information specified at Sec. 438.10(g)(1) about the grievance system to all providers and subcontractors at the time they enter into a contract.

Sec. 438.416 Recordkeeping and reporting requirements.
The State must require MCOs and PIHPs to maintain records of grievances and appeals and must review the information as part of the State quality strategy.

Sec. 438.420 Continuation of benefits while the MCO or PIHP appeal and the State fair hearing are pending.
(a) Terminology. As used in this section, "*timely" filing* means filing on or before the later of the following:
(1) Within ten days of the MCO or PIHP mailing the notice of action.
(2) The intended effective date of the MCO's or PIHP's proposed action.
(b) Continuation of benefits. The MCO or PIHP must continue the enrollee's benefits if—
(1) The enrollee or the provider files the appeal timely;
(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;
(3) The services were ordered by an authorized provider;
(4) The original period covered by the original authorization has not expired; and
(5) The enrollee requests extension of benefits.
(c) Duration of continued or reinstated benefits. If, at the enrollee's request, the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, the benefits must be continued until one of following occurs:
(1) The enrollee withdraws the appeal.
(2) Ten days pass after the MCO or PIHP mails the notice, providing the resolution of the appeal against the enrollee, unless the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.
(3) A State fair hearing Office issues a hearing decision adverse to the enrollee.
(4) The time period or service limits of a previously authorized service has been met.
(d) Enrollee responsibility for services furnished while the appeal is pending. If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's or PIHP's action, the MCO or PIHP may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in Sec. 431.230(b) of this chapter.

Sec. 438.424 Effectuation of reversed appeal resolutions.
(a) Services not furnished while the appeal is pending. If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PIHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.
(b) Services furnished while the appeal is pending. If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO or the PIHP or the State must pay for those services, in accordance with State policy and regulations.

Subpart H--Certifications and Program Integrity

Sec. 438.604 Data that must be certified.
(a) Data certifications. When State payments to an MCO or PIHP are based on data submitted by the MCO or PIHP, the State must require certification of the data as provided in Sec. 438.606. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) Additional certifications. Certification is required, as provided in Sec. 438.606, for all documents specified by the State.

Sec. 438.606 Source, content, and timing of certification.

(a) Source of certification. For the data specified in Sec. 438.604, the data the MCO or PIHP submits to the State must be certified by one of the following:

(1) The MCO's or PIHP's Chief Executive Officer.

(2) The MCO's or PIHP's Chief Financial Officer.

(3) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PIHP's Chief Executive Officer or Chief Financial Officer.

(b) Content of certification. The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of the data.

(2) To the accuracy, completeness and truthfulness of the documents specified by the State.

(c) Timing of certification. The MCO or PIHP must submit the certification concurrently with the certified data.

Sec. 438.610 Prohibited Affiliations with Individuals Debarred by Federal Agencies.

(a) General requirement. An MCO, PCCM, PIHP, or PAHP may not knowingly have a relationship of the type described in paragraph (b) of this section with the following:

(1) An individual who is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

(2) An individual who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in paragraph (a)(1) of this section.

(b) Specific requirements. The relationships described in this paragraph are as follow:

(1) A director, officer, or partner of the MCO, PCCM, PIHP, or PAHP.

(2) A person with beneficial ownership of five percent or more of the MCO's, PCCM's, PIHP's, or PAHP's equity.

(3) A person with an employment, consulting or other arrangement with the MCO, PCCM, PIHP, or PAHP for the provision of items and services that are significant and material to the MCO's, PCCM's, PIHP's, or PAHP's obligations under its contract with the State.

(c) Effect of Noncompliance. If a State finds that an MCO, PCCM, PIHP, or PAHP is not in compliance with paragraphs (a) and (b) of this section, the State:

(1) Must notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement.

(d) Consultation with the Inspector General. Any action by the Secretary described in paragraphs (c)(2) or (c)(3) of this section is taken in consultation with the Inspector General.